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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/731,699 | 12/09/2003 | Darren A. Janzig | 1023-331US01 | 3259 |
| 28863 | 7590 | 06/24/2005 | | |
| SHUMAKER & SIEFFERT, P. A. 8425 SEASONS PARKWAY SUITE 105 ST. PAUL, MN 55125 | | | EXAMINER GREENE, DANA D | |
| | | | ART UNIT 3762 | PAPER NUMBER |

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,699

Applicant(s)

JANZIG ET AL.

Examiner

Dana D. Greene

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10-29-04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference characters not mentioned in the description: 403A and 403B. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7, 8, 11, 12, 14-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Wirtzfeld et al. (US 4,399,820, hereinafter "Wirtzfeld"). Wirtzfeld is considered to disclose:

a least two modules, each of the modules comprising a housing (see col. 4, ln. 5-20, Wirtzfeld). The disclosed pacemaker and measuring probe are considered to anticipate the claimed modules because the pacemaker and measuring probe receive power or signals from one another in the same manner that the modules receive power or signals from each other;

a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the modules, wherein the coupling module permits motion of the two modules along at least one axis of motion (see col. 4, ln. 5-20, Wirtzfeld). The disclosed stimulation catheter is considered to anticipate the claimed coupling module because both devices define a lumen between the modules and permits the motion of the two modules along at least one axis of motion.

With reference to claims 3, 8, and 22 Wirtzfeld is considered to disclose a coupling module that permits motion of the two modules along at least two axes of motion (see col. 4, ln. 5-30, fig. 1, Wirtzfeld). The disclosed stimulation catheter lead is considered to anticipate the two axes of motion because the stimulation catheter lead has a permissible motion that is both horizontal and vertical.

Referring to claims 5 and 23, Wirtzfeld is considered to disclose at least one of the two modules comprising a control module containing electronic components (see col. 4, ln. 5-10, Wirtzfeld). The disclosed electronic circuit component is considered to anticipate the claimed electronic component because both devices are associated with the electrical functions of implantable medical devices.

With reference to claims 11, 14, and 15 Wirtzfeld is considered to disclose a coupling module of a circular cross-sectional shape, a semi-circular cross-sectional shape and a rectangular cross-sectional shape (see col. 4, ln. 5-15, Wirtzfeld).

Referring to claims 16-17, Wirtzfeld is considered to disclose a coupling module made of metal (see col. 4, ln. 30-40, Wirtzfeld). The disclosed metallic element is considered to anticipate the claimed metal module because both configurations enable communication between the two modules.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2 and 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Reischl et al. (US 6,176, 879 B1, hereinafter "Reischl"). Wirtzfeld is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed overmold encapsulation. However, Reischl is

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considered to disclose the claimed modules encased in biocompatible housings (see col. 5, ln. 15-20, Reischl). It would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with the biocompatible housing material of Reischle for the purpose of sealing the modules against contamination and holding the modules in a fixed position relative to one another.

With reference to claim 6, Wirtzfeld is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed IMD thickness. However, Reischl discloses the smallest dimension of its housing to be between 4 millimeters and 8 millimeters (see col. 2, ln. 25-30, Reischl). It would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with Reischl for the purpose of reducing the size of the implantable medical device and reducing limits on the locations within the human body in which the IMD can be practically implanted.

Claims 4 and 9-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Bradley (US 6,490,486 B1, hereinafter "Bradley"). Wirtzfeld is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed at least two lumens. Bradley is considered to disclose multiple lumens (see col. 3, ln. 1-20, Bradley). It would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with Bradley for the purpose of providing independent interconnection paths that are isolated and separate from each other.

Claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Wirtzfeld in view of Schroepel (US 5,776,169, hereinafter "Schroepel"). Wirtzfeld is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed bellows section of the coupling module. However, Schroepel is considered to disclose a bellows hinge (see col. 5, ln. 15-20, Schoreppel). It would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with those of Schroepel for the purpose of enhancing the flexibility of the coupling module or catheter lumen.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1 and 2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/731,638. The two modules of the claimed application possess an identical housing to that of the copending application. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have

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been obvious to one of ordinary skill in the art to provide an implantable medical device for implantation in the head of a patient with variations of a first and second module including a flexible overmold to cover the modules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

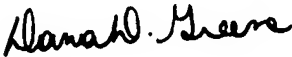
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



George Manuel
Primary Examiner